

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
_____)	MDL No. 2419
)	Dkt. No 1:13-md-2419 (FDS)
THIS DOCUMENT RELATES TO:)	
)	
All Actions)	
_____)	

**SAINT THOMAS ENTITIES' MOTION TO RECONSIDER
MDL ORDER NO. 7**

Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health (collectively referred to as the “Saint Thomas Entities”) file this Motion to Reconsider the Court’s entry of MDL Order No. 7 (Docket #438) (“MDL Order No. 7”) entered on September 18, 2013, and in support show as follows:

INTRODUCTION

The Saint Thomas Entities, who have only recently become parties to this Multi-District Litigation,¹ respectfully request that the Court reconsider MDL Order No. 7. This case-management order does not affect the rights or responsibilities of the Affiliated Defendants,² who are under a separate stay. It only operates against a nebulous group of hospitals, clinics, and other healthcare providers—who, for the most part, have not yet made appearances in this Court³—known collectively as the “Unaffiliated Defendants.” What these Unaffiliated

¹ See Conditional Transfer Order CTO-17 (Docket #409) (Sept. 9, 2013) (*May v. Ameridose, LLC*) and CTO-18 (Docket #434) (Sept. 17, 2013) (*Hester v. Ameridose, LLC* and *Wiley v. Ameridose, LLC*).

² For consistency, the Saint Thomas Entities will use the terms defined by the Court in MDL Order No. 7.

³ A few have made limited appearances for the purpose of objecting to third-party subpoenas, and the Court has made provision for these limited appearances.

Defendants have in common is that they have been notified about or sued for alleged “injuries arising from the contamination of the injectable steroid methyl-prednisolone acetate at the New England Compounding Pharmacy facility in Framingham, Massachusetts.”⁴ Until recently, the Plaintiffs’ Steering Committee (“PSC”) has chosen not to bring these Unaffiliated Defendants into the MDL, yet at the same time, it has assured this Court that it has been working with these entities and individuals who they misleadingly represent to have concurred with the PSC’s actions. Under the circumstances, the Court should not take the lack of written objections to date to mean that there is any consensus. To the contrary, the Saint Thomas Entities believe that the other Unaffiliated Defendants are as concerned about MDL Order No. 7 as they are and expect that the Court will be hearing from them in short order as a raft of new cases begin moving into this Court.⁵

Indeed, contrary to the representations of the PSC, the revised case-management order proposed by the PSC⁶—the same day as the Court’s last status conference on September 12, 2013—did not reflect any agreement or even a vetting of the issues with the Unaffiliated Defendants. Instead, the PSC widely circulated copies of its proposal to a number of hospitals, clinics, and other health care providers that it has contacted in connection with its attempts to force them into its one-sided mediation program.

The PSC’s actions appear to be calculated to achieve a quick resolution without having to do its own work. As noted, instead of filing suits and bringing the Unaffiliated Defendants into

⁴ See Order of February 12, 2013, from the Judicial Panel on Multidistrict Litigation (“JPML”) establishing an MDL in this Court styled *In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.*, MDL No. 2419 (Feb. 12, 2013) (JPML Docket #119).

⁵ Some of the other Unaffiliated Defendants named in the *May* action referenced in note 1, *supra*, filed objections to the proposed case-management order on September 16, 2013 (Docket #433).

⁶ See Motion for Entry of Revised Case Management Schedule by Lead Counsel (Docket #421) (“PSC Motion”).

the MDL—or any other court for that matter—the PSC sent “scores of”⁷ third-party subpoenas to the Unaffiliated Defendants and their witnesses. These subpoenas were highly objectionable for the reasons set forth in the third-party objections.⁸ Moreover, now that the Unaffiliated Defendants are being sued and served, the PSC wants to defer submission of its Master Complaint until *after* the Unaffiliated Defendants have had to answer dozens of lengthy complaints. The Saint Thomas Entities have been named in approximately 100 new cases filed in the past couple of weeks, and most of these complaints are around 50 pages long. The vast amount of work that will be occasioned on the Saint Thomas Entities in simply responding to these voluminous complaints is in no way justified by the PSC’s stated desire to obtain information about the anticipated defenses from the answers. They can simply read the answers that the Saint Thomas Entities have previously filed in Tennessee lawsuits that were subsequently dismissed.

Even more remarkably, the PSC does not appear to have been gathering the medical records of its own clients at the same time it has asked this Court to set an entirely unrealistic case management schedule, including the determination of bellwether plaintiffs only a few months from now. Judge Eldon Fallon, who presided over the Vioxx MDL, has advocated for the process of selecting a few representative—known as “bellwether”—cases for initial trials as an effective means for resolving MDLs, but it must be done with care and process.⁹ Based on

⁷ PSC Motion at 1.

⁸ See, e.g., *Objection to PSC’s Subpoena by Martin Kelvas* (Docket #263) (subsequently withdrawn based on agreement of parties); see also Docket ##218-222, 231-232, 236, 241, 244, 246, 250, 252, 254, 256-257, 259-261, 266, 269, 273, 275, 279, 288, 298, 300, 303-308, 311, 314, 317, 327, 334, 338, 342, 345, 358, 365, 368, 372, 383, 400.

⁹ Eldon E. Fallon, Jeremy T. Grabill & Robert Pitard Wynne, *The Problem of Multidistrict Litigation: Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323, 2323-25 (June 2008).

his experience and that of other MDL courts, Judge Fallon defines important process considerations for making such determinations.¹⁰ As experienced MDL courts have concluded, the selection process is critical to the success of any bellwether program because without truly representative cases, the Court and parties cannot have any confidence in the results.¹¹ In this case, however, the PSC asked the Court to set an overly ambitious deadline for determination of this incredibly important issue *without even proposing a process*. Under such circumstances, “[l]ittle credibility will be attached to this process, and it will be a waste of everyone’s time and resources”¹² and ultimately derail resolution of the MDL—much like the PSC’s failed mediation program.

The result of the PSC’s unorthodox practices is that the parties who are affected by MDL Order No. 7 are either not before the Court or have not become parties to this MDL until just recently. That is why there has been virtually no opposition to the PSC’s proposals as to the Unaffiliated Defendants. The Saint Thomas Entities thus respectfully request that the Court reconsider its MDL Order No. 7, entertain the Saint Thomas Entities’ objections to a number of the provisions contained in the case-management proposal unilaterally put forth by the PSC, and revise the order accordingly. The Saint Thomas Entities also request the Court to afford sufficient time and opportunity for the other Unaffiliated Defendants coming into the MDL to be heard as well.

¹⁰ Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2325-26.

¹¹ *In re Yasmin and Yaz (Drospirnone) Mktg., Sales Practices and Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2010 WL 4024778, at *2 (S.D. Ill. Oct. 13, 2013); *see also In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019-20 (5th Cir. 1997); Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2325-26.

¹² *In re Yasmin*, 2010 WL 4024778, at *2.

BACKGROUND

On February 12, 2013, the Judicial Panel on Multidistrict Litigation (“JPML”) issued an order establishing an MDL in this Court styled *In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.*, MDL No. 2419. The JPML order ordered all cases “relating to injuries arising from the contamination of the injectable steroid methyl-prednisolone acetate at the New England Compounding Pharmacy facility in Framingham, Massachusetts” into this Court for pretrial purposes. JPML MDL No. 2419 (Docket #119 at 1 (Feb. 12, 2013)).

By virtue of its bankruptcy proceeding, New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (“NECC”) is subject to an automatic stay of all liability actions pending against it. And the PSC has agreed to a stay of discovery as to NECC and the Affiliated Defendants “until further order of the court, to be revisited at each status conference.” PSC Motion (proposed order) (Docket #421-1). Further, in the Court’s August 15, 2013 “Order on Mediation” (Docket #394) (“Mediation Order”), the Court has provided for a stay of discovery as to any Unaffiliated Defendants who entered into the program outlined in the order (“Mediation Program”) by filing an election to participate by September 23, 2013. *See* Mediation Order at 9. According to the Court’s official docket sheet, as of September 24, 2013, only three such parties had opted into the Mediation Program. As a result of these developments, the only “parties” who are not subject to a discovery stay are the Unaffiliated Defendants who have not opted into the Mediation Program.

As noted above, the Saint Thomas Entities—and upon information and belief, a majority of the Unaffiliated Defendants—have not been parties to the MDL until only recently. At the time of this Court’s status conference last month, the Saint Thomas Entities had only one

pending action against them in state court in Tennessee.¹³ Shortly before the status conference this month, some of the Saint Thomas Entities were served with a handful of lawsuits filed in the U.S. District Court for the Middle District of Tennessee. The first of these suits was transferred to the MDL by order of September 9, 2013 (CTO-17)—only a few days before the last status conference where the PSC submitted its Motion.

The Court considered the PSC’s Motion at the September 12 status conference. Although the Court made some revisions to the PSC’s proposed CMO in response to the objections of a couple of parties,¹⁴ it did not have the benefit of the positions and concerns of a vast number of the purported dozens of Unaffiliated Defendants, including the Saint Thomas Entities. Now that these Unaffiliated Defendants are becoming parties to the MDL, the Court should expect to hear from others as well.

ARGUMENT AND AUTHORITIES

I. The Proposed CMO Was Not Properly Vetted

In its Motion, the PSC represents that it circulated its proposal to, solicited comments from, and accommodated certain requests of “the defendants (both affiliated and unaffiliated)” PSC Motion at 2. It further states that “NECC and the Affiliated Defendants have no objections to the proposed schedule.” *Id.* at 3. What the PSC did not mention to the Court is that

¹³ Earlier this year, the Saint Thomas Entities were defendants in three other cases in Tennessee state court, but those cases were voluntarily dismissed by the plaintiffs, and the one pending case did not become removable under this Court’s May 31, 2013 Order (Docket #170) until September 6, 2013, when the plaintiffs filed an amended complaint adding the Affiliated Defendants. *See* Notice of Removal in *O’Brien v. Saint Thomas Outpatient Neurosurgical Center, LLC*, No. 3:13-cv-00936 (M.D. Tenn.) (Docket #1).

¹⁴ *See* Docket ##432 & 433. ARL BioPharma, Inc. filed very limited objections to the PSC’s Motion, focusing on the effect of participation in the mediation, *see* Docket #432, and it has since entered into the mediation program under an agreement for a stay of discovery, Docket #442, so its objection is hardly representative of the far greater number of Unaffiliated Defendants who have not consented to participate in the mediation program.

a number of Unaffiliated Defendants sent emails to the PSC indicating that they did not join in the submission and affirming that they were not subject to the Court's jurisdiction because they had only filed a limited appearance objecting to a PSC-issued subpoena. *See Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 350 (1999) ("In the absence of service of process (or waiver of service by the defendant), a court ordinarily may not exercise power over a party the complaint names as defendant." (citations omitted)). To the Saint Thomas Entities' knowledge, not one of the Unaffiliated Defendants consented to the PSC's proposal; like the Saint Thomas Entities, they were simply not in a position to object.¹⁵

II. The Pleadings Requirements Need Balance

A. The Responsive Pleading Date Should Be Stayed for All Parties

Like discovery, the responsive pleadings deadline is stayed for NECC, the Affiliated Defendants, and anyone participating in the Mediation Program. It is also stayed for Unaffiliated Defendants in every state except for Alabama, Kentucky, Louisiana, Nevada, Ohio, and Tennessee. The Saint Thomas Entities are in Tennessee and so are not subject to the stay. Instead, they have been ordered to file responsive pleadings, answers, or motions to dismiss in every case that is transferred to the MDL by the latter of October 9, 2013, or the expiration of the deadline for filing under the Federal Rules of Civil Procedure. This state of affairs means that the Saint Thomas Entities will be required to respond to at least 100 new lawsuits in the next month, and more complaints are being filed each day before the statute of limitations runs. As noted, the complaints in each case are approximately 50 pages, each containing multiple counts and hundreds of numbered paragraphs that these defendants must seek to dismiss or respond.

¹⁵ In addition to not being subject to the Court's jurisdiction, any written objection from the Saint Thomas Entities would have been improper because the Court's Order on Central Enforcement of Subpoenas (Docket #193) permitted affected attorneys to make limited appearances only for the purposes of contesting subpoenas.

That exercise is unjustified—especially where the stated basis for requiring answers at this time is for the PSC to “obtain information” about their defenses.

Notably, although the Saint Thomas Entities would be required to file its motions to dismiss in every case filed to date, the schedule provides that the PSC’s responses to any motions to dismiss are stayed and that the Court will set a later briefing schedule—meaning that these motions are highly unlikely to be resolved at an early stage. Although the order appreciates the importance of an early resolution of these threshold motions, it defers any decision pending a further order. This deferral deprives the Saint Thomas Entities of their ability to have their motions to dismiss heard at the earliest practicable time.

The Saint Thomas Entities have already provided answers in the *Neely*, *May*, and *Reed* cases in Tennessee, and the PSC could simply review those answers rather than require the pointless expenditure of substantial resources to file responsive pleadings in so many cases at one time. Further, as explained below in part II.B, the purpose of having master and short-form pleadings is to streamline the process such that the parties can obtain the necessary information about the others’ legal positions without requiring volumes of duplicative documents. Accordingly, the Saint Thomas Entities respectfully request that their responsive pleadings deadlines be stayed pending resolution of the master pleadings schedule, as discussed below, or at the very least for an additional 60 days so that the Saint Thomas Entities can have adequate time to prepare and file responsive pleadings and motions.

B. The Master Pleading Process Is to Streamline the MDL Proceedings

The Court and PSC appreciate the benefits of having master pleadings and short-form pleadings, but MDL Order No. 7 deprives the Unaffiliated Defendants—at least those in the states of Alabama, Kentucky, Louisiana, Nevada, Ohio, and Tennessee—of the time and resource-saving benefits of having such a process by requiring these defendants to file

traditional, “long-form” (paragraph-by-paragraph) responsive pleadings or motions to dismiss in every case filed thus far. Under the current version of MDL Order No. 7, the Unaffiliated Defendants in the specified states, including the Saint Thomas Entities, will be required to keep filing long-form answers for the foreseeable future, at a substantial burden to them (and to the Court’s electronic filing system) without any corresponding benefit.

Accordingly, the Saint Thomas Entities request that the Court revise the case-management order to require: (i) a Master and proposed Short-Form Complaint by November 5, 2013; (ii) a Master and proposed Short-Form answer at least 30 days later; and (iii) deadlines for filing Short-Form Complaints and Answers in individual cases.

III. The Bellwether Deadlines Are Premature

The PSC is aggressively pushing this MDL to bellwether trials on an unrealistic schedule. It appears that the goal is to get dates in place so that it can pressure the Unaffiliated Defendants into procedures and processes designed to comply with those deadlines. The PSC has the process exactly backwards. The bellwether order needs to come first, and then deadlines can be set accordingly.

In appropriate circumstances, bellwether trials (also referred to as test cases) can be used to glean important information about the claims of the litigation as a whole. *See* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.315 (“[T]o produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases.”). Bellwether procedures have been used in an increasing number of mass tort MDLs. *See* Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2324-25.¹⁶ As the Fifth Circuit has aptly summarized:

¹⁶ The term bellwether “is derived from the ancient practice of bellring a wether (a male sheep) selected to lead his flock. The ultimate success of the wether selected to wear the bell was

A bellwether trial designed to achieve its value ascertainment function for settlement purposes or to answer troubling causation or liability issues common to the universe of claimants has as a core element representativeness -- that is, the sample must be a randomly selected one of sufficient size so as to achieve statistical significance to the desired level of confidence in the result obtained. Such samples are selected by the application of the science of inferential statistics. The essence of the science of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole.

In re Chevron U.S.A., Inc., 109 F.3d 1016, 1019-20 (5th Cir. 1997). As a result, “[i]t is critical to a successful bellwether plan that an honest representative sampling of cases be achieved.” *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2010 WL 4024778, at *1 (S.D. Ill. Oct. 13, 2013); *see also* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.315 (“[T]est cases should produce a sufficient number of representative verdicts and settlements to enable the parties and the court to determine the nature and strength of the claims, whether they can be fairly developed and litigated on a group basis, and what range of values the cases may have if resolution is attempted on a group basis. The more representative the test cases, the more reliable the information about similar cases will be.”). As Judge Fallon indicated, “[i]f bellwether trials are to serve their twin goals as informative indicators of future trends and catalysts for an ultimate resolution, the transferee court and the attorneys must carefully construct the trial-selection process. . . . Any trial-selection process that strays from this path will likely resolve only a few independent cases and have a limited global impact.” Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2343.

Based on his extensive experience in the Vioxx and Propulsid MDLs, Judge Fallon has set out important principles for selecting bellwether trials. He suggests that although there is no “one-size-fits-all” procedure, there are certain sequential steps that should be followed in crafting

determined by whether the flock had confidence that the wether would not lead them astray, and so it is in the mass tort context.” *Chevron*, 109 F.3d at 1019.

the protocols and processes. First, the MDL court must be in a position to catalogue the “Entire Universe of Cases,” meaning that it “conduct[s] a census of the entire litigation and identif[ies] all the major variables.” *Id.* at 2344. The next step is for the court and the attorneys for both sides to “creat[e] a pool of cases that accurately represents the different divisions within the MDL from which the bellwether cases will be selected.” *Id.* at 2346. Important to this step is deciding the size of the pool— “[i]f the pool is too small, then there is a risk that too few of the major variables will be properly represented.” *Id.* at 2347. To fill the pool, there are different methods—random selection, selection by the MDL court, and selection by the attorneys. *Id.* at 2348-49. And there are many variables within each strategy for filling the pool, all of which need to be geared to finding a truly representative, and therefore, credible sampling. *Id.* at 2348-60. After the trial-selection pool has been determined, the parties conduct case-specific discovery. *Id.* at 2360. Then the third step is to select individual cases from the pool, which also can be done in a variety of ways depending on the facts and circumstances. *Id.* at 2360-65. The PSC has not outlined—much less adhered to—any of these steps.

First, the PSC has not demonstrated that bellwether trials would be appropriate in these cases. *See, e.g., Auchard v. Tenn. Valley Auth.*, No. 3:09-CV-54, 2011 U.S. Dist. LEXIS 14771, at *11-14 (E.D. Tenn. Feb. 2, 2011) (finding, after initial discovery, that bellwether cases were not appropriate because, based on the known information, the cases were not numerous enough (having 450 plaintiffs) and there was insufficient commonality between the cases).

Second, assuming that test trials would be proper and useful here, it is premature to set deadlines when the universe of potential bellwether plaintiffs is far from known at this time. Many new cases are in the process of being filed in or transferred to this Court. The Saint Thomas Entities suspect that they are not the only ones who have only recently been served with

lawsuits, as almost no one who is actually subject to MDL Order No. 7 has raised objections. Further, with applicable one-year statute of limitations running soon in Tennessee and some of the other jurisdictions involved in the MDL, the Saint Thomas Entities expect that more lawsuits will be filed in the next couple of weeks. And the Centers for Disease Control list indicates that there will be patients in other states with longer statutes of limitations who will likely file later in the coming months. Without any understanding of what the universe of potential bellwether plaintiffs will be, it is premature to set deadlines for making binding choices.

Third, no bellwether selection procedure has been established. The PSC has indicated that a bellwether order will be negotiated and presented to the Court at a later date, but that, again, puts the cart before the horse. The Fallon article demonstrates the complexity and importance of that process, which should not be rushed. *See, e.g., In re: Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, No. 1:00-1898, MDL 1358 (SAS), M21-88, 2007 WL 1791258, at *3 (S.D.N.Y. June 15, 2007) (approving plan developed after investigation and discovery revealed particular variables in litigation census). By way of comparison, in the vaginal mesh litigation, the MDL court for Boston Scientific entered multiple orders outlining the considerations for how a bellwether trial plan could be conducted and the process of selecting bellwether plaintiffs took over 9 months—which was more than 18 months after the MDL was first established. *See, e.g.,* Pretrial Orders #22 (Nov. 2, 2012), #51 (Aug. 7, 2012), #54 (Aug. 29, 2012) (case selection rounds 1 & 2), in *In re Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2326 (S.D. W. Va.), available at <http://www.wvsc.uscourts.gov/MDL/boston/orders.html> (last visited Sept. 24, 2013). Here, the PSC wants the process completed in a matter of a few months, less than a year after the MDL was first established, and at a time when it is clear that a large percentage of cases have yet to be transferred to this MDL.

Fourth, there is virtually no data from which to determine the matter. As noted above, the PSC has thus far not focused on gathering medical records for the individual plaintiffs—records that are critical to assessing suitability and making decisions as to whether there are sufficiently representative plaintiffs. *See Morgan v. Ford Motor Co.*, No. 06-1080 (JAP) (Consolidated), 2007 U.S. Dist. LEXIS 36515, at *41-42 (D.N.J. May 17, 2007) (providing for Rule 26 conference and disclosures before parties’ selection of bellwether cases); *cf. Abrams v. Ciba Specialty Chems. Corp.*, No. 08-00068-WS-B, 2008 U.S. Dist. LEXIS 86487, at *16-19 (S.D. Ala. Oct. 23, 2008) (demonstrating the importance of having data and discovery to determine bellwether plaintiffs).

Because the PSC has yet to propose any procedure, it would be premature to brief all the considerations that the Court should factor into a bellwether plan—such as the extent to which the parties will agree to a *Lexecon* waiver for cases transferred into the MDL,¹⁷ the effect of the stays as to other defendants on the development of the bellwether claims, the necessity of vetoes or strikes, and other matters that will undoubtedly impact the Court’s ultimate decision on whether and how to craft a bellwether procedure. The purpose of this brief is to demonstrate that a great deal more work needs to be done—and many more parties should be heard—before the Court is positioned to make those decisions. The current schedule for resolving the bellwether issue does not permit a sufficient opportunity for that to occur.

¹⁷ In *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 34 (1998), the U.S. Supreme Court held that the MDL transfer statute, 28 U.S.C. § 1407, does not permit the transferee court to try cases that were not originated under its jurisdiction absent agreement by the parties. In *In re Yasmin*, the court found “such a waiver to be critical to the success of th[e] bellwether] endeavor.” 2010 WL 4024778, at *1.

CONCLUSION AND PRAYER

For these reasons, Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health respectfully request that the Court: (i) grant this motion for reconsideration; (ii) rescind MDL Order No. 7; (iii) entertain briefing and argument from all affected Unaffiliated Defendants on the matter of these case-management issues; (iv) alternatively, and at the very least, stay the deadlines for the Unaffiliated Defendants to file responsive pleadings to the numerous cases still being transferred into this MDL Court; and (v) grant such other and further relief to which the Saint Thomas Entities are entitled.

Respectfully submitted,

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*Motions for *Pro Hac Vice* Admission to be Applied For

CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 26th day of September, 2013.

/s/ Michael E. Pikel, Jr.
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